REMARKS

In the Office Action, claims 1, 6-8, 11-18, 20, 21, 24-29, 44, 47, 48 and 50-54 are rejected under 35 U.S.C. § 102 or, in the alternative, under 35 U.S.C. §103; and claims 1-82 are rejected under 35 U.S.C. § 103. Applicants believe that the rejections have been overcome as discussed below in further detail.

At the outset, claims 1-82 have been canceled without prejudice or disclaimer as previously discussed. Therefore, the anticipation and/or obviousness rejections with respect to same have been rendered moot and thus should be withdrawn.

Further, Applicants have provided new claims 83-95. Applicants respectfully submit that claims 83-94 should be considered patentable over the cited art of record even if properly combinable.

Of the new claims, claims 83 and 90 are the sole independent claims. Claim 83 recites a two part dialysis solution that includes a bicarbonate concentration and an electrolyte concentrate wherein the bicarbonate concentrate and the electrolyte concentrate include a physiological amount of sodium ranging from about 100 mmol/L to about 173 mmol/L, and wherein the two part dialysis solution does not include acetate. Claim 90 recites a method of providing dialysis to a patient. The method includes providing a two part dialysis solution including a bicarbonate concentrate and an electrolyte concentrate wherein the bicarbonate and electrolyte concentrates include a physiological amount of sodium that ranges from about 100 mmol/L, to about 173 mmol/L, and wherein the two part dialysis solution does not include acetate. The method further includes mixing the bicarbonate concentrate and the electrolyte concentrate to form a mixed solution, wherein the mixed solution is used during dialysis.

Applicants have uniquely discovered that the claimed invention can provide ready-to-use bicarbonate based solutions that can be effectively and sterilely administered to the patient during therapy. The ready-to-use formulations can include a number of integrated mechanisms to facilitate the safe and effective use of the bicarbonate-based solutions during medical therapy as claimed. See, Specification, page 10, lines 13-18.

For example, the claims recite, in part, that the bicarbonate and electrolyte concentrates include a physiological amount of sodium that ranges from about 100 mmol/L to about 173 mmol/L. See, Specification, for example, page 3, lines 15-16; and Tables 2A-2C. In this regard,

if the concentrates remain unmixed prior to patient administration (e.g., the frangible connector remains unbroken), this would necessarily ensure that sodium is administrated to the patient in a physiological amount. See, Specification, for example, page 10, lines 28-31.

Even if properly combinable, Applicants believe that the cited art of record is distinguishable from the claimed invention. In the Office Action, the Patent Office cites to U.S. Patent No. 5,211,643 ("Reinhardt") or U.S. Patent No. 5,122,516 ("Watanabe") and further the combination of U.S. Patent No. 5,871,477 ("Isono") in view of Watanabe, U.S. Patent No. 4,630,727 ("Feriani"), van Bommel et al., and Reinhardt in support of the alleged anticipation and obviousness rejections. At a minimum, the cited references fail to disclose or suggest a two-part dialysis solution with a bicarbonate concentrate and an electrolyte concentrate wherein the bicarbonate and electrolyte concentrates include a physiological amount of sodium that ranges from about 100 mmol/L to about 173 mmol/L as required by the claimed invention.

As previously discussed, the Patent Office relies on Reinhardt or Watanabe in support of the anticipation or alternative obviousness rejections and further primarily relies on Isono in support of the obviousness rejection. With respect to Reinhardt, this reference provides a solution that includes 76 mmol/L of sodium (e.g., Concentrate A) in a first concentrate and further includes 196 mmol/L of sodium in a second concentrate (e.g., Concentrate B). See, Reinhardt, example 1, column 6 at line 66 to column 7 at line 16. Clearly, this is different from a two-part solution as claimed that includes a physiological amount of sodium that ranges from about 100 mmol/L to about 173 mmol/L in both the bicarbonate and electrolyte concentrates. Thus, Reinhardt on its own is clearly distinguishable from the claimed invention for at least this reason.

With respect to the Watanabe reference, this reference provides a preparation for blood dialysis that includes two compositions including a first powdery composition with solid electrolytes and a liquid acid and a second powdery composition with sodium hydrogen carbonate and glucose. See, Watanabe, column 2, lines 41-46. In the examples, the components of the powder compositions are provided in amounts (e.g., mmols) where the preparation is prepared by dissolving the two powder compositions in a "prescribed amount of water." See, Watanabe, column 2, lines 53-56. Yet, nowhere does Watanabe provide any indication of the specific volume of this "prescribed amount of water." Clearly, this fails to disclose or suggest

any specific concentration of the components in solution, let alone a specific physiological concentration of sodium that ranges from about 100 mmol/L to about 173 mmol/L in both the bicarbonate and electrolyte concentrates as claimed. Further, Watanabe requires the use of acetate in each of its examples in contrast to the claimed bicarbonate-based solutions that do not include acetate. Thus, Watanabe on its own is clearly distinguishable from the claimed invention for at least these reasons.

With respect to the Isono reference, this reference at best provides guidance with respect to the specific concentration of components, such as sodium, in a mixed solution. Indeed, Isono provides mixing of the electrolyte solution and the bicarbonate into a peritoneal dialysate that contains, for example, sodium at a concentration of from 90 to 150 mEq/l. See, Isono, column 6, line 14-21. Thus, nowhere does Isono on its own disclose or suggest sodium in a physiological amount that ranges from about 100 mmol/L to about 173 mmol/L in both the bicarbonate and electrolyte concentrate solution parts as required by the claimed invention.

Even if combinable, the cited art fails to cover the claimed invention. Again, Reinhardt provides sodium at 76 mmol/L in one concentrate and sodium at 196 mmol/L in another concentrate. This clearly contrasts the claimed invention to the extent that it effectively teaches away from same where, again, the claimed bicarbonate-based solutions require a physiological amount of sodium in both the bicarbonate and electrolyte concentrates as recited above.

Moreover, Watanabe requires the use of acetate in further contrast to the claimed two part solution as discussed above. Further, the Isono reference provides no guidance with respect to the specific sodium concentration in the electrolyte and bicarbonate concentrate, let alone the specific physiological concentration of sodium that is required in both the bicarbonate and electrolyte concentrates as claimed and as discussed above. Moreover, Watanabe cannot be relied on to provide any further guidance with respect to this aspect of the claimed invention. Again, the Watanabe reference is too general in disclosure where it fails to provide any specific concentration level of its components, such as sodium, and further where the emphasis of this reference relates to the solid component parts of the preparation and not the resulting solution thereof.

With respect to the remaining references, the Feriani reference is primarily relied on for its alleged teaching regarding a twin-chamber bag in which the first chamber is filled with

bicarbonate-containing fluid and the second chamber is filled with an acid fluid; and the van Bommel reference is primarily relied on for its purported teaching regarding hemodialysate and continuous renal replacement therapy. See, Office Action, pages 4 and 5. To justify its position, Applicants respectfully submit that the Patent Office has relied on hindsight reasoning to arrive at the claimed invention based on the alleged teachings of the cited art in any hypothetical combination. Therefore, Applicants do not believe that the cited art, even if properly combinable, can be modified to cover a two part bicarbonate-based solution that includes, in part, a physiological amount of sodium that ranges from about 100 mmol/L to about 173 mmol/L and further does not include acetate as claimed. Again, the claimed two part solution can be readily and sterilely made and further facilitate the safe and effective use of same. Accordingly, Applicants respectfully submit that pending claims 83-95 are patentable over the cited art of record and further submit that the present application is in condition for allowance in view of same.

Respectfully submitted,

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